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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

United States of America,

Plaintiff,

v.

Case No.: 2:21-cv-00184

Complaint

PCPLV LLC d/b/a Pinnacle
Compounding Pharmacy, Ofir Ventura,
Cecilia Ventura, Brandon Jimenez, Robert
Gomez, Gomez & Associates, Inc., Rock'n
Rob Enterprises, Amir Shalev, D.P.M., AS
Enterprises, Inc., and Ivan Lee Goldsmith,
M.D.;

Defendants.

The United States of America ("the United States" or the Government"), on behalf of the United States Department of Defense ("DOD") and the United States Department of Veterans Affairs ("VA"), brings this action against defendants PCPLV LLC d/b/a Pinnacle Compounding Pharmacy, Ofir Ventura, Cecilia Ventura, Brandon Jimenez, Robert Gomez, Gomez & Associates, Inc., Rock'n Rob Enterprises, Amir Shalev, D.P.M., AS Enterprises, Inc., and Ivan Lee Goldsmith, M.D. (collectively referred to herein as "Defendants"), and alleges as follows:

I. Introduction

1. This is a civil action brought by the United States against the defendants under the False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733, and the common law, to recover treble damages sustained by, and civil penalties and restitution owed to, the United States for Defendants’ illegal conduct.

2. Between February 2015 and November 2015, Defendants Ofir Ventura and Cecilia Ventura (collectively referred to herein as “the Venturas”) and Brandon Jimenez (“Jimenez”), were all co-owners and members of PCPLV LLC d/b/a Pinnacle Compounding Pharmacy (“Pinnacle”). The owners and members of Pinnacle knowingly and willfully engaged in illegal kickback schemes pursuant to which they caused Pinnacle to pay substantial kickbacks to various third-party marketers in exchange for those marketers arranging for the referral of prescriptions for compounded drugs¹ to Pinnacle. The kickbacks paid to these marketers consisted of a substantial share of the revenue that the marketers’ referrals generated for Pinnacle. These arrangements violated the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b).

3. Defendant Robert Gomez, in his individual capacity and as owner of Gomez & Associates, Inc., and Rock’n Rob Enterprises (collectively referred to herein as “Gomez”), was among the third-party marketers that knowingly and willfully received illegal kickbacks from Pinnacle through his corporate entities. Pursuant to those agreements, Gomez carried out campaigns to directly solicit patients, including TRICARE beneficiaries and beneficiaries of the Civilian Health and Medical Program of the Department of Veterans Affairs (“CHAMPVA”), to accept prescriptions for compounded medications, and

¹ Compounding is a practice in which a licensed pharmacist combines, mixes, or alters ingredients of a drug in response to a prescription to create a medication tailored to the medical needs of an individual patient. See U.S. Food & Drug Administration, *Compounding and the FDA: Questions and Answers*, <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers> (last visited Jan. 28, 2021). For example, a patient with an allergy to a particular ingredient in a commercially-available medication may benefit from a compounded medication in certain circumstances. *Id.* Compounded medications often come in the form of topical creams or sprays. Compounded medications are typically much more expensive than commercially-available medications.

1 arranged for those prescriptions to be referred to Pinnacle, which agreed to pay substantial
2 kickbacks in return. Some patients were even offered financial compensation by third-party
3 marketers, including Gomez, for agreeing to accept prescriptions for compounded medicine.
4 Gomez, through his corporate entities, paid illegal kickbacks to patients in exchange for
5 their agreement to try compounded medications from Pinnacle. Gomez also knowingly and
6 willfully paid illegal kickbacks to physicians directly in exchange for the physicians' writing
7 prescriptions for compounded medications to be referred to Pinnacle, including Ivan Lee
8 Goldsmith, M.D. ("Goldsmith"), Amir Shalev, D.P.M. ("Shalev"), some of which were
9 paid to AS Enterprises, Inc. ("AS Enterprises"), a corporation in which Shalev served as a
10 director at all relevant times herein.

11 4. Upon information and belief, the Venturas and Jimenez likewise knowingly
12 and willfully engaged in illegal kickback schemes pursuant to which they caused Pinnacle to
13 pay physicians directly for the referral of prescriptions for compounded drugs to Pinnacle.
14 For example, Ofir Ventura and Brandon Jimenez hosted dinners with physicians who
15 prescribed a large number of compounded drugs to Pinnacle, including Goldsmith and
16 Shalev. Upon information and belief, the Venturas and Jimenez knowingly and willfully
17 caused Pinnacle to directly pay illegal kickbacks to AS Enterprises to induce Shalev to
18 continue writing numerous prescriptions for expensive and unnecessary compounded
19 medications from Pinnacle. Pinnacle's third-party marketer, Gomez, also knowingly and
20 willfully engaged in illegal kickback schemes with physicians and, through his corporations,
21 made payments directly to physicians, including Goldsmith and Shalev, in exchange for
22 these physicians writing numerous prescriptions for Pinnacle's compounded medications.
23 The kickbacks paid to these physicians likewise consisted of a substantial share of the
24 revenue that the physicians' prescriptions generated for Pinnacle. These arrangements also
25 violated the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b).

26 5. Through these schemes, Defendants knowingly presented and/or caused to
27 be presented claims to the TRICARE and CHAMPVA programs that were false or
28 fraudulent because they were tainted by kickbacks to marketers, physicians, and patients,

1 and did not arise from a valid prescriber-patient relationship and were otherwise
2 unnecessary. As a result of this conduct, Defendants are liable under the False Claims Act,
3 31 U.S.C. § 3729, *et seq.* (the FCA), and the federal common law.

4 **II. Jurisdiction and Venue**

5 6. This Court has subject-matter jurisdiction over this action pursuant to 28
6 U.S.C. §§ 1331 and 1345 and 31 U.S.C. § 3732(a) and (b).

7 7. This Court has personal jurisdiction over defendants under 31 U.S.C. §
8 3732(a), because they have adequate minimum contacts with the United States of America
9 and the State of Nevada to make the assertion of personal jurisdiction sufficient to satisfy
10 due process.

11 8. Venue is proper in this action in the District of Nevada under 28 U.S.C. §
12 1391(b) – (c) and 31 U.S.C. § 3732(a), because Defendants can all be found in, reside in, or
13 have transacted business within this Court’s jurisdiction, and acts that they committed in
14 violation of the FCA, AKS and federal common law occurred within this district.

15 **III. The Parties**

16 9. Plaintiff in this action is the United States of America, suing on behalf of its
17 agencies the DOD, including DOD component the Defense Health Agency (“DHA”),
18 which administers the TRICARE program, and the VA, including VA component the
19 Veterans Health Administration Office of Community Care (“VHAOCC”), which
20 administers the CHAMPVA program.

21 10. At all times relevant herein, Defendant PCPLV LLC, d/b/a Pinnacle
22 Compounding Pharmacy was a Nevada limited liability company with its operations based
23 in Las Vegas, Nevada. At all times relevant to this Complaint, Pinnacle was engaged in the
24 business of providing medical care to, among others, individuals who were TRICARE and
25 CHAMPVA beneficiaries. At all times relevant to this Complaint, Pinnacle acted by and
26 through its vice principals, Ofir Ventura, Cecelia Ventura, and Brandon Jimenez.

27 11. Defendant Ofir Ventura, who resides in Las Vegas, Nevada, was, at all times
28 relevant herein, a co-owner, member, and/or officer of Pinnacle. Ofir Ventura was actively

involved in managing and directing the daily operations at Pinnacle. At all times relevant herein, Ofir Ventura acted in his capacity as a vice principal of Pinnacle. Ofir Ventura is also liable in his individual capacity for the conduct alleged herein, as he knowingly and willfully made or caused to be made false claims for payment to the United States through and on behalf of Pinnacle in violation of the AKS

12. Defendant Cecilia Ventura, who resides in Las Vegas, Nevada, was, at all times relevant herein, the Manager of Pinnacle, as well as a co-owner, member, and/or officer of Pinnacle. Cecilia Ventura was actively involved in managing and directing the daily operations at Pinnacle, including in submitting claims for payment. At all times relevant herein, Cecelia Ventura acted in her capacity as a vice principal of Pinnacle. Cecelia Ventura is also liable in her individual capacity for the conduct alleged herein, as she knowingly and willfully made or caused to be made false claims for payment to the United States through and on behalf of Pinnacle in violation of the AKS.

13. Defendant Brandon Jimenez, who resides in Las Vegas, Nevada, was, at all times relevant herein, a co-owner, member, and/or officer of Pinnacle. Jimenez was actively involved in managing and directing the daily operations at Pinnacle. At all times relevant herein, Brandon Jimenez acted in his capacity as a vice principal of Pinnacle. Jimenez is also liable in his individual capacity for the conduct alleged herein, as he knowingly and willfully made or caused to be made false claims for payment to the United States through and on behalf of Pinnacle in violation of the AKS.

14. Defendant Robert Gomez, who resides in Las Vegas, Nevada, was, at all times relevant herein, the President, Secretary, Treasurer, and/or a Director, as well as a co-owner, of Gomez & Associates, Inc. and Rock'n Rob Enterprises. Gomez was actively involved in managing and directing the daily operations at Gomez & Associates, Inc., and Rock'n Rob Enterprises. At all times relevant herein, Robert Gomez acted in his capacity as a vice principal for Rock'n Rob Enterprises and Gomez & Associates, Inc. to cause these corporations to pay and receive illegal kickbacks. Gomez is also liable in his individual

1 capacity for the conduct alleged herein, as he knowingly and willfully caused the submission
2 of false claims for payment for payment to the United States in violation of the AKS.

3 15. At all times relevant herein, Defendant Gomez & Associates, Inc., was a
4 Nevada corporation with its principle place of business in Henderson, Nevada. Gomez &
5 Associates, Inc., marketed topical compounded prescription creams and other
6 pharmaceutical products directly to patients throughout the United States, including
7 TRICARE and CHAMPVA beneficiaries and paid and received illegal kickbacks for
8 referrals to federal healthcare programs. At all times relevant to this Complaint, Gomez &
9 Associates acted by and through its vice principal, Gomez.

10 16. At all times relevant herein, Rock'n Rob Enterprises, was a Nevada
11 corporation with its principle place of business in Henderson, Nevada. Rock'n Rob
12 Enterprises marketed topical compounded prescription creams and other pharmaceutical
13 products directly to patients throughout the United States, including TRICARE and
14 CHAMPVA beneficiaries, and paid and received illegal kickbacks for referrals to federal
15 healthcare programs. At all times relevant to this Complaint, Rock'n Rob Enterprises acted
16 by and through its vice principal, Gomez.

17 17. Defendant Amir Shalev, D.P.M. ("Shalev"), was, at all times relevant herein,
18 a Doctor of Podiatric Medicine licensed to practice in the State of Nevada, and a director
19 and owner of AS Enterprises, Inc. Shalev prescribed topical compounded prescription
20 creams and other pharmaceutical products directly to patients throughout the United States,
21 including TRICARE and CHAMPVA beneficiaries. At all times relevant herein, Shalev
22 also acted in his capacity as a vice principal for AS Enterprises, Inc. which received
23 kickback payments for the unnecessary prescriptions Shalev wrote. Shalev is also liable in
24 his individual capacity for the conduct alleged herein, as he knowingly and willfully caused
25 the submission of false claims for payment for payment to the United States in violation of
26 the AKS.

27 18. Defendant AS Enterprises, Inc. is a Nevada corporation with its principle
28 place of business in North Las Vegas, Nevada. Shalev was compensated through illegal

kickback payments to AS Enterprises, Inc., by Pinnacle and Gomez in exchange for prescribing topical compounded prescription creams and other pharmaceutical products directly to patients throughout the United States, including TRICARE and CHAMPVA beneficiaries. At all times relevant to this Complaint, AS Enterprises, Inc., acted by and through its vice principal, Shalev.

19. Defendant Ivan Lee Goldsmith, M.D. (“Goldsmith”), was, at all times relevant herein, a Doctor of Medicine licensed to practice in the State of Nevada. Goldsmith prescribed topical compounded prescription creams and other pharmaceutical products directly to patients throughout the United States, including TRICARE and CHAMPVA beneficiaries. Goldsmith received illegal kickback payments for writing these prescriptions.

IV. Background

A. The False Claims Act and Anti-Kickback Statute

20. The FCA provides, in part, that any entity that (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, is liable to the United States for damages and penalties. 31 U.S.C. §§ 3729(a)(1)(A)-(B).

21. To show that an entity acts “knowingly” under the FCA, the United States must prove that the entity, with respect to the information: (1) has actual knowledge of the falsity of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. The United States is not required to prove that the entity had the specific intent to defraud the United States. 31 U.S.C. § 3729(b)(1).

22. A claim for reimbursement from a federal health care program, including the TRICARE and CHAMPVA programs, for items or services resulting from a violation of the AKS “constitutes a false or fraudulent claim for purposes of [the False Claims Act].” 42 U.S.C. § 1320a-7b(g).

23. The AKS arose out of congressional concern that financial inducements may corrupt referral decisions, undermine the goals of ensuring fair competition for federal funds and a market driven by quality of care rather than financial incentives, impose higher costs on federal health care programs, and divert federal funds towards goods and services that are medically unnecessary, of poor quality, or even harmful to patients. To protect the federal health care programs from these harms, Congress enacted a prohibition against offering, soliciting, paying, or receiving kickbacks in any form. Specifically, the AKS makes it illegal for an individual or entity to knowingly and willfully:

[S]olicit[] or receive[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
 (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
 (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

The AKS also makes it illegal for an individual or entity to knowingly and willfully:

[O]ffer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
 (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
 (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

Id. § 1320a-7b(b).

24. The AKS contains several statutory exceptions setting forth certain circumstances under which the AKS's prohibitions against remuneration do not apply. *See* 42 U.S.C. § 1320a-7b(b)(3). Additionally, the United States Department of Health and Human Services Office of Inspector General has promulgated “safe harbor” regulations that identify payment practices that are not subject to the AKS because such practices are

1 unlikely to result in fraud or abuse. *See* 42 C.F.R. § 1001.952. Safe harbor protection is
2 afforded only to those arrangements that meet all the specific conditions set forth in the safe
3 harbor.

4 **B. The TRICARE Program**

5 25. TRICARE (formerly known as CHAMPUS) is a federal health care program,
6 as defined in the AKS, that is administered by DHA, a component of the DOD. TRICARE
7 provides health care insurance for active duty military personnel, military retirees, and
8 military dependents.

9 26. TRICARE contracts with Express Scripts, Incorporated (“ESI”) to administer
10 its prescription drug coverage program, including processing and paying claims for
11 reimbursement from TRICARE for compounded prescription drugs.

12 27. At all relevant times, TRICARE covered compounded drugs that are
13 medically necessary and proven to be safe and effective. *See* 32 C.F.R. § 199.4(g)(15).
14 Compounding is the practice in which a licensed pharmacist or physician combines, mixes,
15 or alters the ingredients of a drug to create a medication tailored to the needs of an
16 individual patient. A patient may need a compounded drug, for example, if he or she is
17 allergic to an ingredient in a manufactured drug.

18 28. From at least March 2014 to June 2015, TRICARE reimbursed pharmacies
19 for all the ingredients in a compounded drug. During this period, retail or mail-order
20 pharmacies generally were paid the “average wholesale price” of each ingredient in a
21 compounded drug minus a negotiated discount.

22 29. A provider, including a pharmacy or a physician, seeking reimbursement
23 from TRICARE must comply with TRICARE’s anti-fraud and abuse provisions. 32 C.F.R.
24 § 199.9(a)(4). Fraudulent situations include commission and kickback arrangements with
25 independent contractors. *Id.* § 199.9(c)(12).

26 30. Fraud or abuse by a pharmacy or physician may result in the denial of the
27 pharmacy or physician’s claims or the exclusion or suspension of the pharmacy or physician
28 from participation in the TRICARE program. 32 C.F.R. §§ 199.9(b), (f).

1 31. TRICARE regulations specify that “[a]ll fraud, abuse, and conflict of interest
2 requirements [in section 199.9] are applicable to the TRICARE pharmacy benefits
3 program.” 32 C.F.R. § 199.21(p). TRICARE’s contract with ESI also incorporates the
4 provisions of 32 C.F.R. § 199.

5 32. To receive reimbursement from TRICARE for compounded drugs, a
6 pharmacy must enter into a Provider Agreement with ESI, TRICARE’s pharmacy benefits
7 manager.

8 33. ESI’s Provider Agreements incorporate ESI’s Provider Manuals as part of
9 those agreements. The ESI Provider Manuals in effect during the relevant time period
10 required pharmacies to be aware of and comply with all state and federal law, “including
11 anti-kickback statutes.” The Manuals warned that “[f]ailure to demonstrate compliance
12 with these laws may result in immediate termination by [ESI].”

13 34. As a condition of payment by TRICARE, a pharmacy must comply with the
14 AKS and must not offer or pay anything of value to third parties in exchange for referring,
15 recommending, or arranging for the referral of TRICARE patients for prescriptions to be
16 filled by the pharmacy and reimbursed by TRICARE.

17 35. DHA has exercised its authority to suspend providers under investigation for
18 fraud and abuse, including the payment of kickbacks.

19 36. Each compounded drug claim submitted by a pharmacy for reimbursement
20 from TRICARE generally includes specific representations about the date of service, the
21 patient on whose behalf payment is being sought, the provider who prescribed the
22 medication, and the individual ingredients contained in the compounded drug.

23 **C. The CHAMPVA Program**

24 37. CHAMPVA is a federal health care program, as defined in the AKS, that is
25 administered by VHAOCC, a component of the VA. CHAMPVA provides health care
26 insurance for the qualifying spouses and children of veterans with service-connected
27 disabilities.

1 38. CHAMPVA contracts with OptumRx, Incorporated (“OptumRx”) to
2 administer its prescription drug coverage program, including the processing and payment of
3 claims for reimbursement from CHAMPVA for compounded prescription drugs.

4 39. At all relevant times, CHAMPVA covered compounded drugs that are
5 medically necessary and proven to be safe and effective. *See* 38 C.F.R. § 17.272(a)–(b).

6 40. From at least January 2014 to November 2015, CHAMPVA reimbursed
7 pharmacies for all the ingredients in a compounded drug. During this period, retail or mail-
8 order pharmacies generally were paid the “average wholesale price” of each ingredient in a
9 compounded drug minus a negotiated discount.

10 41. Like with all other federal programs, a pharmacy seeking reimbursement from
11 CHAMPVA must comply with all applicable anti-fraud and abuse provisions, including the
12 FCA and AKS.

13 42. CHAMPVA’s Program Guide encourages CHAMPVA beneficiaries to report
14 providers engaging in fraud and abuse and provides that providers who engage in fraud and
15 abuse may be sanctioned by the Department of Health and Human Services. U.S.
16 Department of Veterans Affairs, CHAMPVA Program Guide 73, 75 (June 2017), *available at*
17 [https://www.va.gov/COMMUNITYCARE/docs/pubfiles/programguides/champva_guide](https://www.va.gov/COMMUNITYCARE/docs/pubfiles/programguides/champva_guide.pdf)
18 [e.pdf](https://www.va.gov/COMMUNITYCARE/docs/pubfiles/programguides/champva_guide.pdf).

19 43. As a condition of payment by CHAMPVA, a pharmacy must comply with
20 the AKS and must not offer or pay anything of value to third parties in exchange for
21 referring, recommending, or arranging for the referral of CHAMPVA patients for
22 prescriptions to be filled by the pharmacy and reimbursed by CHAMPVA.

23 44. Each compounded drug claim submitted by a pharmacy for reimbursement
24 from CHAMPVA generally includes specific representations about the date of service, the
25 patient on whose behalf payment is being sought, the provider who prescribed the
26 medication, and the individual ingredients contained in the compounded drug.

V. Factual Background

A. Pinnacle's Kickback Relationships with Third-Party Marketers

45. The Venturas and Jimenez owned and operated Pinnacle Compounding Pharmacy, located in Las Vegas, Nevada, from at least January 2014 through at least November 2015. The Venturas and Jimenez were at all times the owners of Pinnacle. In addition to owning the pharmacy, the Venturas and Jimenez oversaw and substantially participated in Pinnacle's operations, including marketing, financial control, and claims submission.

46. Pinnacle, at the direction of the Venturas and Jimenez, entered into agreements with independent third-party "marketers," pursuant to which those marketers were paid substantial kickbacks to generate prescriptions for compounded drugs, including compounded topical creams, and arrange for those prescriptions to be referred to Pinnacle, for which Pinnacle could then seek payment from the patient's insurance, including TRICARE and CHAMPVA.

47. The Venturas and Jimenez agreed for Pinnacle to pay those marketers substantial portions of the revenue, including TRICARE and CHAMPVA revenue, that the marketers successfully generated for the pharmacy as a result of those referrals. One of the primary marketers with whom Pinnacle worked was Gomez and Gomez's two businesses: Gomez & Associates and Rock'n Rob Enterprises. The Venturas and Jimenez were responsible for negotiating and approving the various agreements between Pinnacle and Gomez, and the Venturas and Jimenez continued to oversee Pinnacle's relationships with Gomez and other third-party marketers throughout the course of their kickback arrangements. The Venturas and Jimenez agreed to pay these marketers substantial kickbacks because of the large volume of referrals the marketers could bring to Pinnacle. As a result of these relationships, Pinnacle received prescriptions for, and shipped compounded drugs to, patients located throughout the United States.

48. In May 2014, Cecilia Ventura, acting on behalf of Pinnacle entered into a "Consulting Fee Agreement" with Gomez and Rock'n Rob Enterprises. Pursuant to that

1 agreement, the Venturas and Jimenez agreed to share all revenue from prescriptions that
2 Gomez solicited and referred to Pinnacle. The agreement provided that Pinnacle would pay
3 Gomez and Rock'n Rob Enterprises "thirty-five percent (35%) of the gross amount to
4 reimbursed by insurance companies . . . for prescriptions that come from Consultant's
5 Prospective Accounts that are compounds[.]"

6 49. The Venturas and Jimenez knowingly and willfully designed this arrangement
7 with Gomez to induce him to refer prescriptions to Pinnacle or arrange for or recommend
8 the ordering of compounded drugs from Pinnacle, so that the Venturas and Jimenez
9 through Pinnacle could then seek payment for those drugs from insurers like TRICARE and
10 CHAMPVA. Pursuant to each agreement, Pinnacle only compensated these marketers
11 when and if prescriptions were actually referred to Pinnacle. Additionally, the agreements
12 provided that Gomez's compensation would be tied directly to the volume and value of the
13 prescriptions he referred to Pinnacle. Under the terms of the Consulting Fee Agreement,
14 Gomez only received compensation for prescriptions for compounded medications he
15 referred to Pinnacle. Gomez did not receive compensation for non-compounded
16 medications referred to Pinnacle.

17 50. At no time was there an employment relationship between Pinnacle and
18 Gomez. Gomez's Consulting Fee Agreement stated that Gomez and Pinnacle's "status is,
19 and at all times will continue to be, that of independent contractors with respect to each
20 other." The Venturas and Jimenez knew that there was no employment relationship with
21 Gomez.

22 51. Pinnacle's "marketing" agreement with Gomez was simply an arrangement
23 pursuant to which the Venturas and Jimenez agreed to pay third parties for the referral of
24 prescriptions – a practice they knew was wrongful and illegal.

25 52. A purpose of the agreement was to induce Gomez to refer, or arrange for the
26 referral of, prescriptions to Pinnacle. Gomez's Consulting Fee Agreement expressly
27 provided that Gomez would submit to Pinnacle "accounts and physician profiles, including
28 contact information" which Gomez believed would send business to Pinnacle because of

1 Gomez. The Consulting Fee Agreement stated that this information, which would enable
2 the Venturas and Jimenez to solicit and pay for referrals would be sent to “Brandon
3 [Jimenez] and Cecilia [Ventura]’s email.”

4 53. The substantial commissions agreed to by the Venturas and Jimenez
5 incentivized Gomez and other third-party marketers to increase both the value and volume
6 of the prescriptions they generated and referred to Pinnacle, regardless of patient need.

7 54. One way in which these marketers sought to increase prescription volume
8 was to identify, obtain, and refer prescriptions for formulas that would generate as large of a
9 payment as possible for the pharmacy, and in turn a larger kickback for the marketer,
10 regardless of whether the specific formulation was medically necessary. Notably, such
11 conduct is inconsistent with the purpose of compounding, which is to tailor medications to
12 the specific needs of individual patients.

13 55. The Venturas and Jimenez, through Pinnacle, further encouraged this
14 practice by instructing their employee pharmacists to use more expensive ingredients in its
15 compounded prescriptions, even though less expensive ingredients could be used. The
16 Venturas and Jimenez through Pinnacle then provided pre-printed prescription pads to its
17 marketers, including Gomez.

18 56. Many, if not all, of the TRICARE and CHAMPVA beneficiaries who
19 received compounded medications from Pinnacle did not meet with the prescribing
20 physician, pay a co-pay for the medications, despite a co-pay requirement under TRICARE
21 and CHAMPVA’s respective policies, receive instructions on how to use the medications
22 from the prescribing physician, or need or use the expensive compounded medications they
23 received. Many of the TRICARE and CHAMPVA beneficiaries recalled receiving a
24 compounded pain cream and a compounded scar cream from Pinnacle, though a few
25 beneficiaries also received compounded medications in the form of pills or medicinal sprays.
26 On information and belief, most TRICARE and CHAMPVA beneficiaries who received
27 compounded medications from Pinnacle also received refills of the compounded
28 medications without requesting a refill or meeting with a physician to determine if a refill

1 was necessary or appropriate. Some TRICARE and CHAMPVA beneficiaries also received
2 refills of the compounded medications from Pinnacle despite expressly asking that the
3 medications not be refilled. Upon information and belief, Defendants also made kickbacks
4 in the form of waiving or paying required co-pays for many TRICARE and CHAMPVA
5 beneficiaries

6 57. Pinnacle's pharmacy facility was arranged in a manner that was intended to
7 prevent its compounding pharmacists and pharmacy technicians from discovering
8 Pinnacle's prescription scheme. Pharmacy employees noted that Pinnacle's order entry and
9 billing operations, which on information and belief were overseen by Cecilia Ventura, were
10 kept completely separate from the pharmacists who prepared the compound prescriptions,
11 which was highly unusual. Order entry and billing processes are ordinarily handled by
12 pharmacists.

13 58. Pinnacle employees received calls from TRICARE and CHAMPVA
14 beneficiaries, during which the beneficiaries informed Pinnacle they did not request any
15 compounded medications and asked for more information as to why they received the
16 unrequested medications. At least some of the TRICARE and CHAMPVA beneficiaries
17 who contacted Pinnacle to inquire why they received the compounded prescriptions when
18 they did not order the medications were told by Pinnacle's principals or employees that the
19 medications were theirs to keep, free of charge.

20 **B. Gomez's Referrals to Pinnacle and Representative Claims**

21 59. From March 2014 through approximately November 2015, Gomez
22 knowingly and willfully referred prescriptions for compounded drugs to Pinnacle in
23 exchange for the lucrative kickbacks offered by the Venturas and Jimenez in violation of the
24 AKS.

25 60. Gomez generated prescriptions to send to Pinnacle by directly soliciting
26 TRICARE and CHAMPVA beneficiaries to prospective patients, recruiting other third-
27 party "marketers" to likewise directly solicit prospective patients, soliciting physicians to
28 issue prescriptions to Pinnacle for compounded medications in exchange for financial

1 compensation, and by arranging for providers to sign prescriptions that were ostensibly
2 requested by patients during those sales calls. Gomez received and directed illegal kickback
3 payments through his corporate entities. In accordance with the agreement Gomez signed
4 with Cecilia Ventura acting on behalf of Pinnacle, Pinnacle paid Gomez a share of the
5 revenue the pharmacy received for each of the prescriptions that Gomez sent to Pinnacle.
6 Pinnacle provided Gomez with monthly reports detailing which claims generated from his
7 referrals, the physician who prescribed the medications to TRICARE and CHAMPVA
8 beneficiaries, and the amount of his commission as a result of the referrals.

9 61. Gomez specifically targeted TRICARE and CHAMPVA beneficiaries when
10 illegally marketing Pinnacle's compounded medications. To further implement this scheme,
11 Gomez recruited and paid other third-party "marketers" to help him find TRICARE and
12 CHAMPVA beneficiaries who would be willing to try the compounded medications from
13 Pinnacle. Like Gomez's payment arrangement with Pinnacle, these additional third-party
14 marketers were independent contractors who were provided with 1099 forms from Gomez's
15 corporate entities to report any income Gomez paid them. Gomez knowingly and willfully
16 paid these third-party marketers a portion of his commission paid by Pinnacle for the
17 referrals they obtained in violation of the AKS.

18 62. In order to induce TRICARE and CHAMPVA beneficiaries to try Pinnacle's
19 compounded medications, Gomez and his third-party marketers would regularly also offer
20 beneficiaries kickbacks in the form of financial compensation ranging from \$150-\$220, upon
21 information and belief paid from Gomez's corporations, simply for agreeing to receive
22 compounded medications from Pinnacle. These payments would often be made in cash
23 after the TRICARE or CHAMPVA beneficiary received his or her first prescription from
24 Pinnacle in the mail and were knowingly and willfully made in violation of the AKS.

25 63. One method Gomez and the third-party marketers he recruited would use to
26 refer prescriptions for compounded medications to Pinnacle involved asking TRICARE and
27 CHAMPVA beneficiaries if they could photograph the beneficiaries' military identification
28 cards. Gomez and other marketers would also obtain the beneficiaries' social security

1 numbers. This information was then provided by Gomez to physicians, including
2 Goldsmith and Shalev, who were involved in the kickback scheme.

3 64. Gomez also used a pre-printed prescription pads provided by Pinnacle to
4 induce some TRICARE and CHAMPVA beneficiaries to try compounded medications
5 from Pinnacle and had the beneficiaries select the prescriptions in which they were
6 interested.

7 65. Physicians who agreed to work with Gomez to prescribe medications to
8 Pinnacle, including Goldsmith and Shalev, would then issue prescriptions for compounded
9 medications from Pinnacle for these TRICARE and CHAMPVA beneficiaries without ever
10 meeting with the beneficiaries or establishing a physician-patient relationship. TRICARE
11 and CHAMPVA beneficiaries who were induced to accept Pinnacle compounded
12 medications through Gomez were usually not required to pay a co-pay for the medications,
13 even though copays are required under TRICARE and CHAMPVA's respective policies
14 and waiver of copays constitutes an illegal kickback.

15 66. The following are sample claims submitted by Pinnacle to TRICARE or
16 CHAMPVA for prescriptions referred to Pinnacle by Gomez, and for which Gomez
17 received a kickback.

18 a. Patient A² was a patient referred to Pinnacle by Gomez. Pinnacle filled
19 prescriptions 605534 and C401099 for compounded medications for Patient A
20 on or about April 29, 2015 and submitted a claim to TRICARE. TRICARE paid
21 Pinnacle \$18,377.50 for the prescriptions.

22 b. Patient B was a patient referred to Pinnacle by Gomez. Pinnacle filled
23 prescriptions 401107 and C401106 for compounded medications for Patient B
24 on or about April 30, 2015 and submitted a claim to TRICARE. TRICARE paid
25 Pinnacle \$12,633.41 for the prescriptions.

26
27
28 ² The United States will separately provide Defendants with a key identifying the patients who are referenced herein.

c. Patient A was also recruited by Gomez to refer friends and family members with TRICARE insurance to Pinnacle. Patient A, in turn, referred Patient C to Pinnacle on Gomez's behalf. Pinnacle filled prescription 605697 and a second prescription for compounded medications for Patient C on or about April 30, 2015 and submitted a claim to TRICARE. In sum, Pinnacle filled five total prescriptions for Patient A from approximately April 30, 2015 through approximately May 1, 2015, for which TRICARE paid Pinnacle \$41,922.94.

d. Patient A also referred Patient D to Pinnacle on Gomez's behalf in exchange for compensation provided by Gomez. Pinnacle filled prescription 605699 and two other prescriptions for compounded medications for Patient D on or about April 30, 2015 and submitted a claim to TRICARE. TRICARE paid Pinnacle \$12,395.15 for the prescriptions.

67. Between August 2014 and October 2015, Pinnacle made payments totaling more than \$1.3 million to Gomez, through his corporations, for commissions for his referrals to Pinnacle:

Date	Payee	Amount
<u>08/14/2014</u>	<u>Rock'n Rob Enterprises</u>	<u>\$23,832.62</u>
<u>09/15/2014</u>	<u>Rock'n Rob Enterprises</u>	<u>\$39,948.20</u>
<u>10/15/2014</u>	<u>Rock'n Rob Enterprises</u>	<u>\$44,415.02</u>
<u>11/13/2014</u>	<u>Rock'n Rob Enterprises</u>	<u>\$46,248.94</u>
<u>12/15/2014</u>	<u>Rock'n Rob Enterprises</u>	<u>\$41,685.63</u>
<u>01/14/2015</u>	<u>Gomez & Associates, Inc.</u>	<u>\$62,648.08</u>
<u>02/12/2015</u>	<u>Gomez & Associates, Inc.</u>	<u>\$78,570.22</u>
<u>03/13/2015</u>	<u>Gomez & Associates, Inc.</u>	<u>\$80,956.73</u>
<u>03/23/2015</u>	<u>Gomez & Associates, Inc.</u>	<u>\$30,000.00</u>
<u>04/14/2015</u>	<u>Gomez & Associates, Inc.</u>	<u>\$214,791.77</u>
<u>04/23/2015</u>	<u>Gomez & Associates, Inc.</u>	<u>\$22,716.72</u>
<u>05/14/2015</u>	<u>Gomez & Associates, Inc.</u>	<u>\$297,464.16</u>
<u>05/29/2015</u>	<u>Gomez & Associates, Inc.</u>	<u>\$61,633.03</u>
<u>06/05/2015</u>	<u>Gomez & Associates, Inc.</u>	<u>\$116,538.42</u>
<u>06/12/2016</u>	<u>Gomez & Associates, Inc.</u>	<u>\$72,551.07</u>
<u>07/15/2015</u>	<u>Gomez & Associates, Inc.</u>	<u>\$15,727.28</u>
<u>08/12/2015</u>	<u>Gomez & Associates, Inc.</u>	<u>\$33,546.98</u>

09/15/2015	Gomez & Associates, Inc.	\$15,369.10
10/15/2015	Gomez & Associates, Inc.	\$16,191.10
<u>TOTAL</u>		<u>\$1,314,835.07</u>

C. Pinnacle and Gomez's Kickback Relationships with Physicians, Including Goldsmith and Shalev, and Representative Claims

68. In addition to Pinnacle's kickback arrangements with third-party marketers such as Gomez, Pinnacle also entered into kickback arrangements with physicians directly, including Shalev, in which Shalev knowingly and willfully received compensation, through AS Enterprises, from Pinnacle and/or Gomez for writing prescriptions for compounded medications. Shalev's wife, Deborah Shalev, was also compensated by Pinnacle, allegedly for her work as a Pinnacle employee. Pinnacle made these kickback payments to Shalev through AS Enterprises, an entity in which Shalev holds an ownership interest and is a director. Ofir Ventura and Jimenez also invited physicians to attend dinners at Pinnacle's expense, including Goldsmith and Shalev, in order to induce physicians to prescribe compounded medications from Pinnacle.

69. Gomez likewise knowing and willfully entered into kickback arrangements with a number of physicians, including Goldsmith and Shalev, in which he would share a percentage of his commission from Pinnacle with Goldsmith and Shalev in exchange for the physicians prescribing compounded medications from Pinnacle. Upon information and belief, Gomez knowingly and willfully paid and Goldsmith knowingly and willfully accepted cash for these referrals at Goldsmith's request. Gomez, through his corporations, provided payments to Shalev through Shalev's family business, AS Enterprises, which Shalev knowingly and willfully accepted in exchange for the prescriptions which resulted in payment from TRICARE and CHAMPVA. Gomez also provided these physicians pre-printed prescription pads prepared by Pinnacle to assist the physicians in writing numerous prescriptions for Pinnacle's compounded medications.

70. One Pinnacle pharmacist employed by Pinnacle during the relevant time period noted and found it unusual that Goldsmith received discounts from Pinnacle and

1 was sent testosterone, upon information and belief, for use on his patients and for his
2 personal use by Pinnacle.

3 71. Further, when TRICARE and CHAMPVA beneficiaries would return
4 unrequested compounded medications to Pinnacle, those returned medications were
5 typically not discarded, which was proper procedure, but were instead provided to Gomez,
6 who would in turn give the returned medications as “samples” for Goldsmith.

7 72. Numerous TRICARE and CHAMPVA beneficiaries reported receiving
8 compounded prescriptions from Pinnacle without ever requesting these medications at all.
9 These beneficiaries would receive the compounded medications through mail delivery,
10 despite never meeting with the prescribing physician (often Goldsmith or Shalev) prior to
11 receiving the compounded medications. The beneficiaries generally were not required to pay
12 a co-pay for the compounded prescriptions, even though one was required under TRICARE
13 and CHAMPVA’s respective policies. Goldsmith, Shalev, and other physicians issued
14 prescriptions to some or all of these beneficiaries despite the fact that they never consulted
15 with them or established a physician-patient relationship with them.

16 73. Some TRICARE and CHAMPVA beneficiaries even received compounded
17 medications, which they did not request, that were not full (including both half-full and
18 completely empty tubes of medication) and were unlabeled.

19 74. Even the small number of TRICARE and CHAMPVA beneficiaries who
20 were actual patients of physicians such as Shalev and Goldsmith by and large did not
21 discuss a need for compounded medications, did not request or discuss compounded
22 medications with their physician, and did not know why they received compounded
23 medications in the mail from Pinnacle. Goldsmith would also give patients multiple tubes
24 containing compounded medications from Pinnacle at his office directly without providing
25 the patients with a prescription for the compounded medication and without the patients
26 actually requesting the compounded medications. These compounded medications would
27 subsequently be billed to TRICARE and CHAMPVA.
28

1 75. The following are sample claims submitted by Pinnacle to TRICARE or
2 CHAMPVA for prescriptions written by Goldsmith and for which, upon information and
3 belief, Goldsmith knowingly and willfully received a kickback.

4 a. Patient E was a TRICARE beneficiary for whom Goldsmith wrote prescriptions
5 for compounded medications, without first meeting with Patient E and/or
6 establishing a physician-patient relationship with Patient E. Patient E was
7 referred to Pinnacle and Goldsmith by a third-party marketer who offered
8 Patient E compensation in exchange for accepting Pinnacle's compounded
9 medications. From approximately March 24, 2015, through approximately April
10 21, 2015, Pinnacle filled seven prescriptions in total for Patient E, including
11 prescriptions 605171, 603990, and five other prescriptions. Pinnacle filled these
12 prescriptions for compounded medications for Patient E and submitted claims to
13 TRICARE. Patient E did not recall paying a co-pay for these seven prescriptions
14 or receiving any bills for co-pays, even though a co-pay was required for each of
15 the prescriptions under TRICARE's policies. TRICARE paid Pinnacle
16 \$78,463.87 in total for the prescriptions.

17 b. Patient F was a TRICARE beneficiary for whom Goldsmith wrote prescriptions
18 for compounded medications. While Patient F was a patient of Goldsmith's,
19 Patient F was provided two tubes of a compounded medication at Goldsmith's
20 office by a nurse at the end of his office visit without a receiving written
21 prescription provided by Goldsmith for the compounded medication and
22 without requesting or desiring the compounded medication. Patient F did not
23 visit Goldsmith for pain management care and was surprised to be provided
24 compounded medications for pain management but was told the medications
25 "were covered by TRICARE." From approximately September 4, 2014, through
26 approximately May 1, 2015, Pinnacle filled four prescriptions in total for Patient
27 F, including prescriptions C40998, 604797, and two other prescriptions.
28 Pinnacle filled these prescriptions for compounded medications for Patient F

1 and submitted claims to TRICARE. Patient F did not pay a co-pay for the
2 medications, even though a co-pay was required for the medications under
3 TRICARE's policies. TRICARE paid Pinnacle \$25,800.50 in total for the
4 prescriptions.

5 c. Patient G was a CHAMPVA beneficiary for whom Goldsmith wrote
6 prescriptions for compounded medications. Shortly after Patient G became a
7 patient of Goldsmith's, Patient G received several packages of compounded
8 prescription medications in the mail that she did not request and for which she
9 did not receive a prescription. Patient G returned the medications to Goldsmith
10 and asked to stop receiving the compounded medications, but even after her
11 request, she continued receiving additional packages of compounded
12 medications from Pinnacle. Patient G subsequently received a letter from
13 Goldsmith informing her that he no longer wanted her as a patient. From
14 approximately October 2014, through approximately July 2015, Pinnacle filled
15 41 prescriptions in total for Patient G including prescriptions C40998, 604797,
16 and 39 other prescriptions. Pinnacle filled these prescriptions for compounded
17 medications for Patient G and submitted claims to CHAMPVA. Patient G did
18 not pay a co-pay for the medications, even though a co-pay was required for the
19 medications under CHAMPVA's policies. CHAMPVA paid Pinnacle
20 \$283,857.13 in total for the prescriptions.

21 d. In sum, Goldsmith wrote 304 prescriptions for compounded medications to 45
22 different TRICARE or CHAMPVA beneficiaries. TRICARE paid Pinnacle
23 more than \$1.7 million based on prescriptions issued by Goldsmith.
24 CHAMPVA paid Pinnacle more than \$283,000.00 based on prescriptions issued
25 by Goldsmith.

26 76. The following are sample claims submitted by Pinnacle to TRICARE or
27 CHAMPVA for prescriptions written by Shalev and for which, upon information and belief,
28 Shalev knowingly and willfully received a kickback.

- 1 a. Patient H was a TRICARE beneficiary for whom Shalev wrote prescriptions for
2 compounded medications, without first meeting with Patient H and/or
3 establishing a physician-patient relationship with Patient H. Patient H received
4 compounded medications from Pinnacle in the mail after completing an online
5 survey for a “free trial of medication.” Patient H resides in Arizona, while
6 Shalev is licensed to practice podiatry in Nevada. Pinnacle filled prescriptions
7 605708, 605709, and 605712 for compounded medications for Patient H on or
8 about April 30, 2015 and submitted claims to TRICARE. Patient H did not
9 recall paying co-pays for the prescription, even though a co-pay was required
10 under TRICARE’s policies. TRICARE paid Pinnacle \$29,961.40 for these
11 prescriptions.
- 12 b. Patient I was a CHAMPVA beneficiary for whom Shalev wrote prescriptions for
13 compounded medications, without first meeting with Patient I and/or
14 establishing a physician-patient relationship with Patient I. Patient I resides in
15 Tennessee, while Shalev is licensed to practice podiatry in Nevada. Patient I
16 recalled receiving several boxes of compounded medication from Pinnacle in the
17 mail. Patient I did not know why she received the compounded medications and
18 did not request or otherwise order any compounded medications from Pinnacle.
19 From approximately July 2015 through approximately August 2015, Pinnacle
20 filled seven prescriptions in total for Patient I, including prescriptions 061278-00-
21 0, 0612727-00-0, and five other prescriptions. Pinnacle filled these prescriptions
22 for compounded medications for Patient I and submitted claims to CHAMPVA.
23 CHAMPVA paid Pinnacle \$53,144.23 in total for the prescriptions.
- 24 c. Patient J was a CHAMPVA beneficiary for whom Shalev wrote prescriptions for
25 compounded medications, without first meeting with Patient J and/or
26 establishing a physician-patient relationship with Patient J. Patient J resides in
27 Tennessee, while Shalev is licensed to practice podiatry in Nevada. Patient J
28 recalled receiving a phone call asking her to try “a pain cream for her arthritis.”

1 Patient J responded that she was not interested in the mediation, but it was sent
2 to her regardless. Patient J received several bottles of compounded medication
3 from Pinnacle over a period of months. Patient J never spoke with Shalev before
4 he prescribed the medications at issue. From approximately August 2015
5 through approximately October 2015, Pinnacle filled five prescriptions in total
6 for Patient J, including prescriptions 0608900-00-0, 0608901-00-0, and three
7 other prescriptions. Pinnacle filled these prescriptions for compounded
8 medications for Patient J and submitted claims to CHAMPVA. CHAMPVA
9 paid Pinnacle \$63,049.91 in total for the prescriptions.

10 d. Patient K was a CHAMPVA beneficiary who received compounded
11 medications from Pinnacle prescribed by two different physicians, including
12 Shalev, both of whom prescribed the medications without first meeting with
13 Patient K and/or establishing a physician-patient relationship with Patient K.
14 Patient K received compounded medications from Pinnacle in the mail without
15 requesting any such medications. From approximately February 2015 through
16 October 2015, Pinnacle filled approximately 18 prescriptions for compounded
17 medications for Patient K, including prescriptions 0610123-00-0, 0610124-00-0,
18 0607042-00-0, 0607041-00-0, 602387, 602388, 602389, and 11 other
19 prescriptions and submitted claims to CHAMPVA. CHAMPVA paid Pinnacle
20 \$118,665.96 for these prescriptions.

21 e. In sum, Shalev wrote 235 prescriptions for compounded medications to 55
22 different TRICARE or CHAMPVA beneficiaries. In sum, TRICARE paid
23 Pinnacle more than \$295,000.00 in claims based on prescriptions issued by
24 Shalev. CHAMPVA paid Pinnacle more than \$1,199,000.00 in claims based on
25 prescriptions issued by Shalev.

26 77. Between October 2014 and June 2015, Pinnacle made payments totaling
27 more than \$48,000.00 to AS Enterprises, which, upon information and belief, were
28

commission payments paid in exchange for Shalev's prescriptions of compounded medications to Pinnacle:

Date	Payee	Amount
10/15/2014	AS Enterprises, Inc.	\$5,942.60
11/13/2014	AS Enterprises, Inc.	\$4,880.13
12/14/2014	AS Enterprises, Inc.	\$3,490.93
01/14/2015	AS Enterprises, Inc.	\$5,786.11
02/12/2015	AS Enterprises, Inc.	\$3,218.05
03/16/2015	AS Enterprises, Inc.	\$5,971.85
04/15/2015	AS Enterprises, Inc.	\$6,574.90
05/15/2015	AS Enterprises, Inc.	\$9,554.15
06/12/2015	AS Enterprises, Inc.	\$2,904.40
TOTAL		\$48,323.12

78. Gomez also made a series of payments, totaling more than \$10,000.00, to AS Enterprises for "commissions" between June 2014 and September 2014:

Date	Payee	Amount
06/16/2014	AS Enterprises, Inc.	\$3,273.35
07/15/2014	AS Enterprises, Inc.	\$956.23
08/15/2014	AS Enterprises, Inc.	\$3004.00
08/15/2014	AS Enterprises, Inc.	\$496.05
09/15/2014	AS Enterprises, Inc.	\$2,336.13
TOTAL		\$10,065.76

D. Pinnacle's Third-Party Telemarketing and Online Marketing Efforts.

79. Pinnacle's "marketing" efforts, directed at prescribing large amounts of compounded medications to TRICARE and CHAMPVA beneficiaries, did not end with involving third-party marketers such as Gomez. For example, some TRICARE and CHAMPVA beneficiaries recalled receiving compounded medications from Pinnacle after responding to an online advertisement or calling a 1-800 phone line in response to a television advertisement, both of which promised "free trials" of medication. These beneficiaries would subsequently receive compounded medications from Pinnacle in the mail.

1 80. Pinnacle also had “marketers” who would call TRICARE and CHAMPVA
2 beneficiaries, including individuals purporting to be TRICARE or CHAMPVA “adjusters”
3 and promising the beneficiaries no-cost compounded medications. These beneficiaries did
4 not meet with a physician before receiving the medications, generally did not pay a co-pay
5 for the medication, and did not receive instructions from a physician regarding how they
6 should use the compounded medications from Pinnacle.

7 81. The following are sample claims submitted by Pinnacle to TRICARE or
8 CHAMPVA for prescriptions written to TRICARE or CHAMPVA beneficiaries as a result
9 of telephone or internet marketing efforts.

10 a. Patient L was a TRICARE beneficiary for whom Shalev wrote prescriptions for
11 compounded medications, without first meeting with Patient L and/or
12 establishing a physician-patient relationship with Patient L. Patient L received
13 compounded medications from Pinnacle in the mail after receiving a call from
14 an individual identifying himself or herself as a “TRICARE adjuster.” Patient L
15 resides in Ohio, while Shalev is licensed to practice podiatry in Nevada.
16 Pinnacle filled prescription 605713 for compounded medications for Patient L
17 on or about April 30, 2015 and submitted a claim to TRICARE. Patient L did
18 not recall paying a co-pay for the prescription, even though a co-pay was
19 required under TRICARE’s policies. TRICARE paid Pinnacle \$2,755.03 for
20 prescription 605713.

21 b. Patient M was a CHAMPVA beneficiary who received compounded
22 medications from Pinnacle prescribed by Shalev without seeing Patient M
23 and/or establishing a physician-patient relationship with Patient M. Patient M
24 received compounded medications from Pinnacle after responding to a
25 television advertisement for “dental issues.” From approximately August 2015
26 through October 2015, Pinnacle filled approximately seven prescriptions for
27 compounded medications for Patient M, including prescriptions 0612738-00-0,
28 0611548-00-0, 062736-00-0, 0611560-00-0, 062739-00-0, and two other

1 prescriptions and submitted claims to CHAMPVA. CHAMPVA paid Pinnacle
2 \$55,512.11 for these prescriptions.

3 **E. Defendants Were Aware of the Prohibitions of the AKS and Acted Knowingly**
4 **and Willfully**

5 82. Defendants were all familiar with the AKS and its prohibitions.

6 83. For example, Jimenez and Gomez both had sales experience in the health
7 care industry prior to their involvement with Pinnacle. Jimenez previously worked for
8 another compounding pharmacy prior to opening Pinnacle. Gomez worked with Jimenez
9 at this compounding pharmacy, as well, and was subsequently recruited to continue his
10 sales efforts on behalf of Pinnacle.

11 84. Further, the terms of Gomez's "Consulting Fee Agreement," signed by
12 Gomez and Cecelia Ventura make clear that the Venturas, Jimenez, and Gomez were all
13 aware of the AKS and knowingly and willfully created an agreement that violated it.
14 Despite clearly contemplating payments for referrals, Gomez's agreement with Pinnacle
15 specifically states that Gomez was expected to "[c]omply with all federal, state and local
16 laws, statutes, regulations, and requirements of all governmental agencies governing the
17 marketing and promotion of [Gomez]'s services hereunder, which shall include but not be
18 limited to, anti-kickback, FDA, DEA, and to use best efforts under this paragraph not to
19 violate the law."

20 85. The Venturas and Jimenez knew Gomez and its other third-party marketing
21 efforts were referring prescriptions to Pinnacle for TRICARE and CHAMPVA
22 beneficiaries, and that Pinnacle was submitting claims to TRICARE and CHAMPVA for
23 those prescriptions in contravention of the AKS and FCA. The Venturas and Jimenez
24 actively participated in this scheme. For example, Cecilia Ventura entered into the
25 marketing agreement with Gomez on behalf of Pinnacle, the agreement required Gomez to
26 report to Cecilia Ventura and Jimenez, and Cecilia Ventura oversaw Pinnacle's submission
27 of false and tainted claims. Jimenez and Ofir Ventura hosted dinners for physicians to
28 induce them to provide referrals. Upon information and belief, the Venturas and Jimenez

exercised their financial control over Pinnacle to pay lucrative commissions to Gomez and these third-party referral sources to induce them to refer such prescriptions to Pinnacle.

86. Gomez likewise knew that Pinnacle was submitting claims to TRICARE and CHAMPVA for prescriptions that he referred in violation of the AKS and FCA. Gomez knew that the prescriptions he and the third-party marketers he recruited sent to Pinnacle included prescriptions for TRICARE and CHAMPVA beneficiaries. Gomez and the third-party marketers he recruited obtained information about patients' insurance when attempting to induce them to receive compounded prescriptions from Pinnacle. Gomez intended for Pinnacle to seek reimbursement for the prescriptions he referred, including from TRICARE and CHAMPVA, so that Pinnacle would in turn pay him, through his corporations, his agreed upon share of such payments.

87. Goldsmith and Shalev also knew that Pinnacle was submitting claims to TRICARE and CHAMPVA based on prescriptions they wrote in exchange for financial compensation from Gomez, the Venturas, and Jimenez in violation of the AKS and FCA. Goldsmith and Shalev knew that the prescriptions they wrote and sent to Pinnacle included prescriptions for TRICARE and CHAMPVA beneficiaries. Despite knowing their conduct was wrongful, Goldsmith and Shalev intended for Pinnacle to seek reimbursement for the prescriptions they wrote, including from TRICARE and CHAMPVA, so that Pinnacle and Gomez would pay their agreed upon share of any such payments, including through payments to Shalev's entity AS Enterprises as well as provide other incentives such as meals and discounts on other pharmaceutical products.

F. Defendants' Conduct Was Material, and The United States Suffered Damages

88. TRICARE and CHAMPVA paid Pinnacle millions of dollars for prescriptions that were illegally induced by kickbacks to Gomez, Goldsmith, and Shalev.

89. Gomez's referrals to Pinnacle, as well as Goldsmith and Shalev's submission of numerous compounded medication prescriptions to Pinnacle, in exchange for illegal kickbacks, also resulted in TRICARE and CHAMPVA paying millions of dollars for prescriptions tainted by those referrals. Gomez, Goldsmith, and Shalev all knew that

1 the Venturas and Jimenez, through Pinnacle, submitted claims for payment to
2 TRICARE and CHAMPVA that were based on illegal kickback schemes and caused
3 those claims to be submitted.

4 90. At the time TRICARE and CHAMPVA paid these claims, TRICARE and
5 CHAMPVA were unaware of the Defendants' illegal kickback arrangements underlying
6 those claims. The claims for payment submitted to TRICARE as a result of these kickback
7 relationships did not disclose these arrangements to ESI, TRICARE, or CHAMPVA.

8 91. TRICARE and CHAMPVA would never have paid claims submitted by
9 Pinnacle that were induced by illegal kickbacks. By submitting these claims to
10 TRICARE and CHAMPVA, the Venturas and Jimenez, through Pinnacle falsely
11 represented that the claims were not in violation of the AKS and intentionally
12 omitted information regarding its violations of the AKS. TRICARE and CHAMPVA
13 were influenced by and relied on the representation that the submitted claims did
14 not arise from illegal kickback arrangements when paying the claims.

15 92. TRICARE and CHAMPVA also would never have paid claims that
16 were not medically necessary. By submitting these claims to TRICARE and
17 CHAMPVA, the Venturas and Jimenez, through Pinnacle falsely represented that
18 the claims were medically necessary for treatment of TRICARE and CHAMPVA
19 beneficiaries and arose from a proper physician-patient relationship when
20 submitting the claims for payment. Shalev and Goldsmith likewise represented that
21 the prescriptions they wrote were medical necessary and arose from a proper
22 physician-patient relationship when issuing the prescriptions. TRICARE and
23 CHAMPVA will both only pay claims for medications that are medically necessary.
24 TRICARE and CHAMPVA were influenced by and relied on these representations
25 that the submitted claims were medically necessary for the beneficiaries when
26 paying the claims.

First Cause of Action

(False or Fraudulent Claims)

(False Claims Act-31 U.S.C. § 3729(a)(1)(A))

93. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 92.

94. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to an officer or employee of the United States false or fraudulent TRICARE and CHAMPVA claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A); that is, Defendants knowingly made or presented, or caused to be made or presented, to the United States claims for payment for compounded drugs for TRICARE and CHAMPVA patients that were tainted by illegal kickback arrangements.

95. By reason of the foregoing, the United States suffered actual damages in an amount to be determined at trial and therefore is entitled to treble damages under the False Claims Act, plus civil penalties of not less than \$11,665 and not more than \$22,331 per false claim.

Second Cause of Action

(Payment by Mistake)

96. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 92.

97. This is a claim by the United States for the recovery of monies paid directly or indirectly to Defendants by mistake for compounded drugs that were tainted by kickbacks to marketers, physicians, and patients and did not arise from a valid practitioner-patient relationship.

98. The payments made to Defendants, directly or indirectly, were made under the erroneous belief that the claims were not tainted by illegal kickbacks, arose from a valid physician-patient relationship, and were medically necessary for the TRICARE and

CHAMPVA beneficiaries for whom the claims were submitted. TRICARE and CHAMPVA would never have paid the claims if it knew of these circumstances.

99. As a consequence of the conduct and the acts set forth above, Defendants were paid directly or indirectly by mistake by the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

Third Cause of Action

(Unjust Enrichment)

100. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 92.

101. This is a claim by the United States for recovery of monies by which Defendants have been unjustly enriched. Defendants, directly or indirectly, received, accepted, and retained benefits from the United States in the form of payments for claims that were based in fraudulent kickback schemes, did not arise from a valid physician-patient relationship, and were not medically necessary for TRICARE and CHAMPVA beneficiaries.

102. By virtue of the conduct and the acts described above, Defendants were unjustly enriched at the expense of the United States in an amount to be determined, which, under the circumstances, in equity and good conscience, should be returned to the United States.

Prayer for Relief and Jury Demand

WHEREFORE, the United States respectfully prays for judgment in its favor as follows:

a. As to First Cause of Action (False Claims Act), against Defendants, for: (i) statutory damages in an amount to be established at trial, trebled as required by law, and such penalties as are required by law; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

b. As to the Second Cause of Action (Payment Under Mistake of Fact), for: (i) an amount equal to the money paid by the United States through the TRICARE and

1 CHAMPVA programs to, and illegally retained by, Defendants, plus interest; (ii) the costs
2 of this action, plus interest, as provided by law; and (iii) any other relief that this Court
3 deems appropriate, to be determined at a trial by jury.

4 c. As to the Third Cause of Action (Unjust Enrichment), for: (i) an amount
5 equal to the money paid by the United States through the TRICARE and CHAMPVA
6 programs to Defendants, or the amount by which Defendants were unjustly enriched, plus
7 interest; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other
8 relief that this Court deems appropriate, to be determined at a trial by jury.

9 d. And for all other and further relief as the Court may deem just and proper.

10 The United States hereby demands a jury trial on all claims alleged herein.

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12 Respectfully submitted this 2nd day of February 2021.

13
14 NICHOLAS A. TRUTANICH
United States Attorney

15 /s/ Allison C. Reppond
16 ALLISON C. REPPOND
17 Assistant United States Attorney
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